REMARKS/ARGUMENTS

Status of the Claims

Claims 24-25, 27, 30, 32-34, 36, 38-40, 42, 44-46, and 50 are pending.

Amendments to the Claims

Claim 24 has been amended to include the presence of "an acid" in the liquid composition. Support for this amendment is at paragraph [0027] of the specification. In addition, claim 24 has been further amended to include elements recited in dependent claims 26, 28-29, 31, 35, 37, 41, and 43. Accordingly, claims 26, 28-29, 31, 35, 37, 41, and 43 have been canceled. In addition, claims 23 and 47-49 have been canceled. The dependency of claims 27, 30, 32, 36, 38, 42, and 44 has been amended.

No new matter has been added by way of these amendments to the claims.

Discussion of Section 103 Rejections

Claims 23-50 are rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over 70-5191-00-8 (Pfizer Labs, Division of Pfizer Inc., NY, NY 10017 (October 2003)) referred to "Zithromax" in view of U.S. Patent No. 6,365,574 (Singer). Applicants traverse.

Claims 23, 26, 28-29, 31, 35, 37, 41, 43, and 47-49 have been canceled thereby rendering the rejection of these claims moot.

For subject matter defined by a claim to be considered obvious, the Office must demonstrate that the differences between the claimed subject matter and the prior art "are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a); *see also Graham v. John Deere Co.*, 383 U.S. 1, 148 U.S.P.Q. 459 (1966). The ultimate determination of whether an invention is or is not obvious is based on certain factual inquiries including: (1) the scope and content of the prior art, (2) the level of ordinary skill in the prior art, (3) the differences between the claimed invention and the prior art, and (4) objective evidence of nonobviousness. *Graham*, 383 U.S. at 17-18, 148 U.S.P.Q. at 467.

Consideration of the *Graham* factors here indicates that the present invention, as defined by the pending claims, is unobvious in view of the cited Zithromax and Singer references either individually or in combination.

Pending claims 24-25, 27, 30, 32-34, 36, 38-40, 42, 44-46, and 50 are directed to a method of producing a sterile pharmaceutical formulation comprising lyophilized involving, in part, preparing a liquid composition comprising an ethanolate of azithromycin, an acid, and an aqueous solvent. The pharmaceutical formulation produced according to the claimed method contains ethanol in an amount from about 0.005% to about 0.5% by weight.

There is no teaching or suggestion in either the Zithromax or Singer of a method for producing a stable, sterile pharmaceutical formulation comprising lyophilized azithromycin containing ethanol in an amount from about 0.005% to about 0.5% by weight of the pharmaceutical formulation as recited in the pending claims.

Importantly, neither Zithromax nor Singer describe the precise conditions under which a formulation comprising lyophilized azithromycin containing ethanol in the recited amount is produced. For example, specific temperatures and times required for the freezing stage in step (c), primary drying stage in step (d), and secondary drying stage in step (e) are not disclosed in Zithromax or Singer. The conditions for successful lyophilization vary widely for each active ingredient and even for different forms of an active ingredient. Therefore, in view of the limited teachings of the cited references, it would not have been obvious in view of the cited references to produce a lyophilized azithromycin containing ethanol in an amount from about 0.005% to about 0.5% by weight of the pharmaceutical formulation under the specific conditions recited in the pending method claims.

Even if it would have been obvious to combine Zithromax and Singer as the Office Action contends (at page 3), there is no disclosure in either of these references regarding the particular lyophilization cycle (e.g., the temperatures and times for the freezing stage, primary drying stage, and secondary drying stage) necessary to produce a pharmaceutically acceptable formulation of azithromycin with the required ethanol content of from about 0.005% to about 0.5% by weight.

In sum, the combination of Zithromax and Singer does not result in the invention of pending claims 24-25, 27, 30, 32-34, 36, 38-40, 42, 44-46, and 50 and therefore, there is no *prima facie* case of obviousness. Accordingly, Applicants request that the obviousness rejection be withdrawn.

Conclusion

Applicants respectfully submit that the patent application is in condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,

s/ Steven H. Sklar
Steven H. Sklar, Reg. No. 42,154
LEYDIG, VOIT & MAYER, LTD.
Two Prudential Plaza, Suite 4900
180 North Stetson Avenue
Chicago, Illinois 60601-6731
(312) 616-5600 (telephone)
(312) 616-5700 (facsimile)

Date: February 19, 2008